

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NOVOZYMES A/S,

Plaintiff,

v.

GENENCOR INTERNATIONAL, INC. and  
ENZYME DEVELOPMENT CORPORATION,

Defendants.

C.A. No. 05-160-KAJ

**ENZYME DEVELOPMENT CORPORATION'S  
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Enzyme Development Corporation ("EDC"), by its attorneys, responds to Plaintiff Novozymes A/S's ("Novozymes") Complaint for Patent Infringement ("Complaint") as follows:

**ANSWER**

1. EDC admits that the Complaint purports to set forth a patent infringement action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, that this Court has subject matter jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 and 1338, and that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

2. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint.

3. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint.

4. EDC admits the allegations of paragraph 4 of the Complaint.

5. EDC admits that the public record appears to reflect that Novozymes is the owner by assignment of United States Patent No. 6,867,031 (“the ‘031 patent”), that the patent is entitled “Amylase Variants,” and that the ‘031 patent issued on March 15, 2005, but denies the remaining allegations of paragraph 5 of the Complaint.

6. EDC admits that Novozymes contends that the ‘031 patent claims alpha amylases modified by the deletion of the amino acids at positions equivalent to positions 179 and 180, but denies that Novozymes’ statements in paragraph 6 of the Complaint completely or accurately describe all limitations of any or all claims of the ‘031 patent.

7. EDC admits the allegations of paragraph 7 of the Complaint.

8. EDC admits the allegations of paragraph 8 of the Complaint, except that EDC denies it is the sole means of U.S. sales of Genencor’s Spezyme® Ethyl.

9. EDC admits that Novozymes contends that Spezyme® Ethyl is an alpha-amylase that differs from a parent *Bacillus (Geobacillus) stearothermophilus* alpha-amylase by the deletion of two amino acids at positions equivalent to positions 179 and 180 but denies that Novozymes’ statements in paragraph 6 of the Complaint completely or accurately describe Spezyme® Ethyl.

10. EDC denies the allegations of paragraph 10 of the Complaint.

11. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Complaint.

12. EDC denies the allegations of paragraph 12 of the Complaint.

13. EDC denies the allegations of paragraph 13 of the Complaint.

14. EDC denies all other allegations of the Complaint, including in the prayer for relief, that were not expressly admitted above, including those allegations to which EDC is without knowledge or information sufficient to form beliefs as to the truth thereof.

## **AFFIRMATIVE DEFENSES**

### **FIRST AFFIRMATIVE DEFENSE**

15. On information and belief, the '031 patent is invalid for failing to satisfy one or more of the conditions of patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

### **SECOND AFFIRMATIVE DEFENSE**

16. EDC has not infringed any valid or enforceable claim of the '031 patent.

### **THIRD AFFIRMATIVE DEFENSE**

17. On information and belief, the '031 patent is unenforceable due to Novozymes' inequitable conduct in procuring the '031 patent because those owing a duty of candor in prosecution of the '031 patent misrepresented to the Patent Office ("PTO") the significance and unexpected and/or surprising nature of alleged experimental results, and the appropriateness of the design of the alleged underlying experiment, upon which misrepresentations the Examiner relied in allowing the claims of the '031 patent. Specifically, to establish the patentability of the claims that issued as claims 1-5 of the '031 patent over prior art cited by the Examiner during the prosecution, Jason Garbell, Novozymes' patent attorney, submitted an Amendment under 37 C.F.R. 1.111 ("Amendment") to the PTO on September 7, 2004 accompanied by a Declaration of Torben V. Borchert Under 37 C.F.R. 1.132 ("Borchert Declaration"). According to the Borchert Declaration, Dr. Borchert is a Director at Novozymes and an inventor of the '031 patent. The Amendment states that the Borchert Declaration provides evidence of unexpected results over the prior art to rebut the Examiner's rejection of similar claims under 35 U.S.C. 103. The Borchert Declaration asserts that the experimental results presented are statistically significant and surprisingly greater than what would have been expected from the prior art cited by the Examiner. The Examiner, in a Notice of Allowability dated September 21, 2004, stated

that the claims of the '031 patent are allowable based upon the unexpected results presented in the Borchert Declaration which demonstrate that the claims are non-obvious over the prior art.

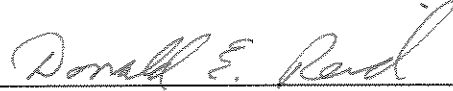
18. On information and belief, on September 3, 2004, Dr. Borchert and Garbell engaged in a personal Interview with the Examiner (the "Examiner"). On information and belief, during the Interview Dr. Borchert and Garbell presented a draft declaration and made, directly and through the draft declaration, statements similar to those described above, on which the Examiner relied to allow claims of the '031 patent.

19. Dr. Borchert, Garbell and Elias Lambiris, Novozymes' other patent attorney of record, each and all owed a duty of candor for prosecution of the '031 patent. On information and belief, Dr. Borchert, Garbell and Lambiris knew or should have known that the results presented in the Borchert Declaration and/or in the Interview are not actually statistically significant, that the poor experimental design precludes drawing the conclusion that the results are unexpectedly or surprisingly greater than those obtained for the prior art enzymes, and that the results are not, in fact, unexpected or surprising. Dr. Borchert, Garbell and Lambiris thus misrepresented the significance and nature of the results presented in the Borchert Declaration to the Patent Office and the Examiner expressly relied upon those misrepresentations in allowing the '031 patent. Therefore, the '031 patent is unenforceable based on inequitable conduct in its prosecution.

#### FOURTH AFFIRMATIVE DEFENSE

20. The '031 patent is unenforceable due to prosecution laches.

MORRIS, NICHOLS, ARSHT & TUNNELL



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May 6, 2005

**CERTIFICATE OF SERVICE**

I, Donald E. Reid, hereby certify that on the 6<sup>th</sup> day of May, 2005 a copy of Enzyme Development Corporation's Answer and Affirmative Defenses was served electronically on the following counsel of record:

Josy W. Ingersoll, Esquire  
Young, Conaway, Stargatt & Taylor LLP  
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A handwritten signature in cursive script, reading "Donald E. Reid", is positioned above a horizontal line.

Donald E. Reid (#1058)